

REMARKS

Claims 16-18, 37 and 41-42 are pending and under examination in the Action.

Claims 16-18, 37, 41 and 42 are rejected under 35 U.S.C. §112, first paragraph. Claims 16-18, 37, 41 and 42 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Rudy et al., *Mol. Med.* 1(6): 625-633 (September 1, 1995).

This Response addresses each of the Examiner's rejections. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

Regarding the rejection of claims 16-18, 37, 41 and 42 under 35 U.S.C. §112, first paragraph, the Examiner contends that the specification does not provide sufficient evidence showing that the claimed method could be used for assaying the reactivity of any cell (i.e., all cells) towards an IDDM autoantigen. The Examiner acknowledges that the specification discloses T cell assays, particularly proliferative and cytokine assays, as set forth in Examples 3-6. However, the Examiner contends that it is unclear how other cell types, e.g., fibroblast or red blood cells, might be involved in IDDM.

In an effort to favorably advance prosecution of the present application, Applicants have amended independent claims 16 and 37 to define "cells derived from the subject" as T-cells. Applicants respectfully submit that the rejection is obviated in view of such amendment. Withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

Claims 16-18, 37, 41 and 42 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Rudy et al., *Mol. Med.* 1(6): 625-633 (September 1, 1995).

Applicants believe that the rejection is based on a determination by the Examiner that the priority date of the claimed subject matter is the filing date of the parent application,

Serial No. 08/663,272, i.e., November 25, 1996. The Examiner recognizes that Applicants have claimed the benefit of priority from Australian PN 1239/95, Australian PN 5172/95, and PCT/AU/00085. However, the Examiner states that these documents do not teach the presently claimed assay, which employs a specified peptide. Specifically, the Examiner alleges that the priority documents do not teach the use of the peptide specified in claim 16, wherein X_1 and X_3 each consist of 0-15 amino acids, or a peptide with X_2 as defined in claims 16 and 37.

Applicants disagree with the Examiner. In the first instance, it is observed that the parent application, Serial No. 08/663,272, was the national phase of PCT/AU/00085 under 35 U.S.C. § 371. The '272 application has a disclosure identical with that of PCT/AU/00085. Therefore, the presently claimed subject matter, which is entitled to the filing date of the '272 application as acknowledged specifically by the Examiner, is also entitled to at least the filing date of PCT/AU/00085, i.e., February 20, 1996.

Furthermore, it is observed that X_2 as defined in claims 16 and 37, is specifically supported by the disclosure of PN 1239/95 (page 2, line 23; and page 3, line 3). Additionally, the characterization of X_1 and X_3 in claim 37, is supported by the disclosure of PN 1239/95 (page 2, line 22). Essentially the same supporting disclosure is found also in PCT/AU/00085. Thus, the subject matter of claim 37 is entitled to the benefit of the filing date of PN 1239/95, i.e., February 20, 1995. Therefore, the rejection of claim 37 and its dependent claims (claim 41-42) as anticipated by Rudy et al. is therefore in error.

As to claim 16, as discussed above, the subject matter of claim 16 is entitled to at least the filing date of PCT/AU/00085, i.e., February 20, 1996. Applicants also direct the Examiner's attention to page 2, line 25 and page 3, line 21-22 of PCT/AU/00085 for disclosure of X_1 and X_3 being 0-15 amino acid residues. As the priority date of February 20, 1996 is

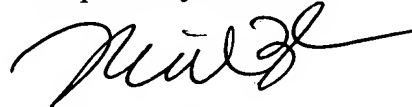
within one year of the publication date of Rudy et al., the Rudy et al. reference is, at best, a reference under §102(a), not §102(b).

In this connection, Applicants provide herewith a Katz declaration, which establishes that the disclosure of the Rudy publication is not by "another", i.e., it is the work of the present inventors. Specifically, the present inventors testified in the Declaration that, while six other individuals are co-authors of the Rudy et al. article, these co-authors are not co-inventors of the subject matter described in the article. Hence, the present inventors are the only inventors of the subject matter which is disclosed in the Rudy et al. article.

Applicants respectfully submit that a publication that occurred less than one year before applicants' application comes within the scope of §102(a) only if the publication is not of applicants' own work. In re Katz, 215 USPQ 14, 18 (CCPA 1982). Because the Declaration has sufficiently established that the work described in the Rudy et al. article is not work by "another" within the meaning of §102(a), Applicants submit that the Rudy et al. article is not prior art under §102(a). As such, withdrawal of the rejection based on Rudy et al. is respectfully requested.

In view of the foregoing amendments and remarks, it is firmly believed that the present application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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